IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
EASTERN DIVISION

LORETTA COX and ALFRED COX, Plaintiffs, v. BOSTON SCIENTIFIC CORP. and PROXY BIOMEDICAL, LTD. Defendants.	)	Court File No. _____ **COMPLAINT** **Jury Trial Demanded**

I. INTRODUCTION

1. Plaintiffs, by their undersigned counsel, bring this Complaint against Defendants Boston Scientific Corporation and Proxy Biomedical, LTD. related to the design, manufacture, marketing, distribution and sale of Defendants' transvaginal mesh products. This action is for compensatory, equitable, injunctive, and declaratory relief. Plaintiffs make the following allegations based upon their individual personal knowledge as to their own acts, and upon information and belief, as well as upon their attorneys' investigative efforts as to Defendants' actions and misconduct, and alleges as follows.

II. PARTIES

2. Plaintiffs Loretta Cox and Alfred Cox are citizens and residents of the State of Georgia. At all relevant times, Plaintiffs lived and resided together as husband and

wife. Plaintiffs have suffered and continue to suffer significant injury as a result of Defendants' transvaginal mesh products and the conduct alleged herein.

3. Defendant Boston Scientific Corporation ("BSC") is a Delaware corporation with its principal place of business located at 1 Boston Scientific Place, Natick, Massachusetts, 01760-1537. BSC develops technology to diagnose and treat conditions related to the pelvic health of women. At all times relevant herein, BSC was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices. All acts and omissions of BSC as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

4. Defendant Proxy Biomedical, LTD. ("Proxy") is an Irish public limited company located in Spiddal Co., Galway, Ireland. Proxy develops technology to diagnose and treat conditions related to the pelvic health of women. At all times relevant herein, Proxy was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices. All acts and omissions of Proxy as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

5. BSC and Proxy are collectively referred to herein as "Defendants."

III. JURISDICTION AND VENUE

6. Plaintiffs are seeking damages in excess of $75,000. This Court has diversity subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(a).

7. Defendants have significant contacts with the Eastern Division of the District of Massachusetts such that they are subject to personal jurisdiction within said district.

8. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in the Eastern Division of the District of Massachusetts.

9. Pursuant to 28 U.S.C. § 1391(a), venue is proper in the United States District Court for the District of Massachusetts.

IV. FACTUAL BACKGROUND

10. Prior to and in 2007, BSC sought and obtained Food and Drug Administration ("FDA") approval to market the Solyx Sling System under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Prior to and in 2005, Proxy sought and obtained FDA approval to market Polyform Synthetic Mesh ("Polyform") under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

11. Proxy Biomedical, Inc. ("Proxy, Inc.") is a United States subsidiary of Proxy. In individual cases, and specifically those cases involving Polyform and related products, Proxy has made an effort to distinguish itself from its wholly owned subsidiary

Proxy, Inc. In the *Hagedorn et al. v. Boston Scientific et al.* matter, Proxy filed a sworn declaration wherein Mr. Peter Gingras, CEO of Proxy, Inc. and Managing Director of Proxy, swears that

> **Proxy, Inc.** is a separate and distinct corporate entity that **provides administrative and business development support for product lines manufactured by Proxy [LTD.], other than the Polyform™ mesh at issue in this litigation....**

12. Proxy manufactures Polyform, which is a non-absorbable synthetic mesh constructed of knitted filaments of polypropylene. Proxy sells Polyform to BSC in Galway, Ireland pursuant to orders BSC sends to Galway, Ireland. Proxy then ships Polyform to BSC's distribution center in Quincy, Massachusetts. The Polyform is shipped to BSC's distribution center in sterile, sheet form to be cut to size and sutured by a surgeon to meet an individual patient's needs. In other words, the Polyform which Proxy ships to BSC is a finished product which is ready to be implanted without the need for alterations and/or modifications.

13. Proxy has conceded that, with regard to Polyform, it is a "manufacturer" as that term is defined in the Biomaterials Access Assurance Act (BAAA). Mulrooney Aff., at 2 (Exhibit A).

14. BSC has an exclusive licensing agreement to distribute Polyform. *See* Distribution Agreement §§ 2.1, 2.2 (Exhibit B); Mulrooney Aff., at 1 (Exhibit A).

15. Proxy maintains continuous and systematic contacts with Massachusetts. Specifically, Proxy's officers regularly communicate and meet with BSC in Massachusetts, and from time-to-time visit BSC in Massachusetts, to address issues

related to the supply and manufacture of the mesh components for BSC's products. Proxy concedes that it has ties to Massachusetts due to its relationship as a supplier and consultant to BSC.

16. Proxy purposefully availed itself of the United States market by marketing its products, including Polyform, through its distributor, BSC, which maintains its principal place of business in Massachusetts. *See* Distribution Agreement §§ 2.1, 2.2 (Exhibit B). Proxy's direct efforts in obtaining 510(k) clearance from the FDA to market Polyform allowed Proxy to avail itself of the United States market.

17. BSC has described Proxy's U.S. National Sales Manager, Jon Rischmiller, as "directly responsible for our mesh business and our key contact at Proxy." As BSC's "key contact at Proxy," Rischmiller met and communicated with BSC in the United States about Polyform and BSC's women's health product business in general, as well as a Polyform pre-clinical study which he was involved in procuring.

18. The Defendants also manufacture and sell a variety of other Pelvic Mesh Products. The Pelvic Mesh Products are products targeted at women who suffer from pain, discomfort, and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. They are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

19. Moreover, the Pelvic Mesh Products contain a monofilament polypropylene mesh intended for the treatment of stress urinary incontinence. Despite claims that this

material is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' Pelvic Mesh Products containing this material. This immune response promotes degradation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh.

20. Defendants' Pelvic Mesh Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse, or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

21. The Defendants have marketed and sold the Pelvic Mesh Products to patients and the medical community at large through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Also utilized are documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the product.

22. At all times relevant to this action, Defendants, intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers,

defects, and disadvantages of the Pelvic Mesh Products and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as safe medical devices when, in fact, Defendants knew that the Pelvic Mesh Products were not safe for their intended purpose and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, catastrophic and permanent injuries.

23. Contrary to the Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Products have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Loretta Cox, making them defective under the law. The defects stem from any or all of the following:

a. the use of polypropylene material in the mesh itself and the immune reaction that results, causing adverse reactions and injuries;

b. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury;

d. the use and design of anchors in the Pelvic Mesh Products which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

e. degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury;

f. the welding of the mesh itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike; and

g. the design of trocars, as devices to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries.

24. The Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Products to fail and cause injury and complications, and has misrepresented the efficacy and safety of the products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

25. Despite the chronic underreporting of adverse events associated with the Defendants' Pelvic Mesh Products and the underreporting of events associated with similarly designed competitor products, enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

26. On October 20, 2008, the FDA issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse events") that had been

reported over a three-year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendants are specified on the list of the manufacturers that are the subject of the notification.

27. On July 13, 2011, the FDA issued a Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of "**continuing serious concern.**" (emphasis added) The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were "**not rare.**" (emphasis in the original) These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh or repair of SUI with mesh kits was more effective than traditional non-mesh repair of pelvic organ prolapse. The FDA conducted a systematic review of the published scientific literature from 1996-2011 and concluded that based thereon, that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non-mesh repair." In the July 13, 2011 Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the

development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendants and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use or labeling.

28. Also in July, 2011, the FDA advised physicians and healthcare practitioners that it continues to evaluate the serious complications and consequences associated with implantation of surgical mesh through transvaginal placement to treat SUI.

29. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of pelvic mesh products in pelvic repair procedures. In its Petition, Public Citizen warned that the transvaginal mesh should be recalled because it offers no significant benefits but exposes patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

30. In early September 2011, the FDA Advisory Panel convened to discuss safety concerns with Pelvic Mesh Products in general. As a result of the meeting, the FDA has called for more clinical studies and tougher regulation on mesh devices and manufacturers, such as Defendants. The Advisory Panel also informed the FDA that they

agreed on the need for more safety studies of the implants as well as labeling changes to warn of potential risks.

31. Defendants have known that some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices (including a medical device known as the Protogen device which was also manufactured, marketed, and sold by Defendants); that there were and are differences between the Defendants' Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; that significant differences exist and existed between the Pelvic Mesh Products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications. The Defendants suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers, or the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Product into Plaintiff Loretta Cox.

32. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of their Pelvic Mesh Products.

33. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products, therefore, in the event of a failure, injury, or complications it is impossible to easily and safely remove them.

34. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

35. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

36. The Defendants provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of their products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff Loretta Cox.

37. The Pelvic Mesh Products implanted into Plaintiff Loretta Cox were in the same or substantially similar condition as they were when they left the possession of Defendants, and in the condition directed by and expected by the Defendants.

38. Plaintiff Loretta Cox and her physicians foreseeably used and implanted the Pelvic Mesh Products, and did not misuse, or alter the Pelvic Mesh Products in an unforeseeable manner.

39. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' Pelvic Mesh Products include, but are not limited to,

mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections in to various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

40. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' Pelvic Mesh, have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

41. Defendants misrepresented to the medical and healthcare community, Plaintiff Loretta Cox, the FDA, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

42. These representations were made by Defendants with the intent of inducing the medical community, Plaintiff Loretta Cox, and the public, to recommend, prescribe, dispense, and purchase their Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or pelvic organ prolapse, all of which evidenced an indifference to the health, safety, and welfare of Plaintiff Loretta Cox.

43. Defendants failed to undertake their duties to properly know the qualities of the Pelvic Mesh Products and in representations to Plaintiff Loretta Cox, and/or to her healthcare providers, concealed and intentionally omitted the following material information:

a. That the Pelvic Mesh Products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. That the risk of adverse events with the Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

c. That the risk of adverse events with the Pelvic Mesh products was not adequately tested and was known by Defendants;

d. That the limited clinical testing revealed the Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

e. That Defendants failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

f. That Defendants were aware of dangers in the Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

g. That the Pelvic Mesh Products were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a

much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

h. That patients needed to be monitored more regularly than usual while using the Pelvic Mesh Products and that in the event the product needed to be removed that the procedures to remove it had a very high failure rate and/or needed to be performed repeatedly;

i. That the Pelvic Mesh Products were manufactured negligently;

j. That the Pelvic Mesh Products were manufactured defectively; and

k. That the Pelvic Mesh Products were designed negligently, and designed defectively.

44. Defendants were under a duty to disclose to Plaintiff Loretta Cox and her physicians, the defective nature of the Pelvic Mesh Products, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

45. Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Pelvic Mesh Products.

46. Defendants' concealment and omissions of material fact concerning the safety of the Pelvic Mesh Products were made to cause Plaintiff Loretta Cox's physicians and healthcare providers to purchase, prescribe, and/or dispense the Product; and/or to mislead Plaintiff Loretta Cox into reliance and cause her to use the Products.

47. At the time these representations were made by Defendants, and at the time the Products were implanted into Plaintiff Loretta Cox, she was unaware of the falsehood of these representations, and reasonably believed them to be true.

48. Defendants knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

49. In reliance upon these false representations, Plaintiff Loretta Cox was induced to, and did allow the Pelvic Mesh Products to be implanted, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiff Loretta Cox and her physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the Pelvic Mesh Products, as described in detail herein.

50. As a result of Defendants' research and testing or lack thereof, Defendants distributed false information, including but not limited to assuring Plaintiff Loretta Cox, the public, and Plaintiff Loretta Cox's healthcare providers and physicians, that the Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or pelvic organ prolapse and were as safe or safer than other products and/or procedures available and on the market. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed

certain results of testing and research to healthcare professionals, Plaintiff Loretta Cox, and the public at large.

51. Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff Loretta Cox, her healthcare providers, and the FDA.

52. The information distributed to the public, the medical community, the FDA, and Plaintiff Loretta Cox by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Pelvic Mesh Products.

53. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff Loretta Cox, regarding the safety of the Pelvic Mesh Products, specifically that the Pelvic Mesh Products did not have dangerous and/or serious adverse health safety concerns, and that the Pelvic Mesh Products were as safe as other means of treating vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

54. Defendants intentionally failed to inform the public, including Plaintiff Loretta Cox, of the high failure rate including erosion, the difficulty of removing the mesh, and the risk of permanent injury.

55. Defendants chose to over-promote the safety, efficacy and benefits of the Pelvic Mesh Products instead.

56. Defendants' intent and purpose in making these misrepresentations was to deceive the public, the medical community, and Plaintiff Loretta Cox; to gain the confidence of the public, the medical community, and Plaintiff Loretta Cox; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Products; and induce Plaintiff Loretta Cox, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Pelvic Mesh Products.

57. Defendants made claims and representations in their documents submitted to the FDA and their reports to the public and to healthcare professionals and in advertisements that the Pelvic Mesh Products did not present serious health risks.

58. These representations, and others made by Defendants, were false when made and/or were made recklessly and without regard to the true facts. These representations, and others made by Defendants, were made with the intention of deceiving Plaintiff Loretta Cox, her healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiff Loretta Cox and her healthcare professionals, to rely on misrepresentations, and caused Plaintiff Loretta Cox to purchase, rely, use, and request the Pelvic Mesh Products and her healthcare professionals to dispense, recommend, or prescribe the Pelvic Mesh Products.

59. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of product known to be dangerous and defective, and/or not as safe as other alternatives. Defendants

utilized direct-to-consumer advertising to market, promote, and advertise the Pelvic Mesh Products.

60. At the time the representations were made, Plaintiff Loretta Cox and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Pelvic Mesh Products. Plaintiff Loretta Cox did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff Loretta Cox discover the false representations of Defendants, nor would Plaintiff Loretta Cox with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

61. Had Plaintiff Loretta Cox known the true facts about the dangers and serious health and/or safety risks of the Pelvic Mesh Products, she would not have purchased, allowed the Pelvic Mesh Products to be implanted in her, or relied on Defendants' Products.

62. At all times relevant herein, the Pelvic Mesh Products were widely advertised and promoted by the Defendants as a safe and effective treatment for vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele. Defendants downplayed the risks posed to stress urinary incontinence and pelvic organ prolapse patients with implantation of the Pelvic Mesh Products.

63. At all times relevant to this action, Defendants knew that the Pelvic Mesh Products were not safe for the patients for whom they were prescribed and implanted, because the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries from erosion, extrusion, infection, sepsis,

chronic foreign body invasion, dense adhesions and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theater for complete removal and results in scarring on fragile, compromised pelvic tissue and muscles.

64. At all relevant times herein, Defendants continued to promote the Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short term efficacy.

65. In doing so the Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Pelvic Mesh Products for treatment of vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

66. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff Loretta Cox and the general public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products including, but not limited to, mesh erosion, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

67. The Pelvic Mesh Products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of pelvic health safety.

V. PLAINTIFFS' EXPERIENCE AND INJURIES

68. On or about December 28, 2010, Plaintiff Loretta Cox was implanted with a surgical mesh sling packaged in the Solyx Sling System. The System included the surgical mesh sling as well as instruments to aid in the placement of the sling. During the same procedure, Plaintiff Loretta Cox was implanted with Polyform Synthetic Mesh. The procedure was performed by Dr. James Dorchak at Doctors Hospital in Columbus, Georgia.

69. The Solyx Sling System implanted in Plaintiff Loretta Cox was designed, manufactured, packaged, labeled, marketed, and sold by BSC. The Polyform Synthetic Mesh implanted in Plaintiff Loretta Cox was designed and manufactured by Proxy and packaged, labeled, marketed, and sold by BSC. The Solyx Sling System and Polyform Synthetic Mesh implanted in Plaintiff Loretta Cox will hereinafter be collectively referred to as "the Products."

70. The Products were implanted in Plaintiff Loretta Cox with the intention of treating her stress urinary incontinence and pelvic organ prolapse, uses for which Defendants marketed and sold the Products.

71. At all times, the Products that were implanted in Plaintiff Loretta Cox were being used for the purposes that Defendants marketed the Products.

72. After, and as a result of the implantation of the Products, Plaintiff Loretta Cox suffered serious bodily injuries, including, but not limited to, pelvic pain, infection, urinary problems, and other injuries. These injuries would not have occurred but for the defective nature of the Products implanted and/or Defendants' wrongful conduct.

73. As a result of having the Products implanted into her, Plaintiff Loretta Cox has experienced significant mental and physical pain and suffering, has required additional medical treatment, will likely be forced to undergo one or more additional surgical procedures, and has sustained permanent injury.

74. As a result of the aforesaid conduct and defective Products manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff Loretta Cox was injured, resulting in severe mental and physical pain and suffering. Such injuries will result in some permanent disability to her person. As a result of such injuries, Plaintiff Loretta Cox has suffered compensatory damages.

75. As a further result of the aforesaid conduct and defective Products manufactured, sold, distributed, advertised, and promoted by Defendants, Plaintiff Loretta Cox was required to and did employ health care providers and incurred, medical, hospital and incidental expenses; further, Plaintiff Loretta Cox is informed and believes, and alleges thereon, that she will be required to incur additional medical, hospital, and incidental expenses.

76. As a further result of the aforesaid conduct and the defective Products manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff Loretta Cox has suffered a loss of earnings and earning capacity and will continue to suffer a loss of future earnings.

VI. CLAIMS FOR RELIEF

COUNT I
NEGLIGENCE

77. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

78. Defendants had a duty to exercise reasonable care in the design, research, manufacture, marketing, advertising, supplying, promoting, packaging, sale, and distribution of their Products, including the duty to assure that the Products would not cause users to suffer unreasonable, dangerous side effects.

79. Defendants failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promoting, advertising, packaging, sale, testing, quality assurance, quality control, and distribution of the Products because Defendants knew or had reason to know that using the Products created a high risk of unreasonable and dangerous side effects, including, but not limited to, severe erosion of the vaginal wall and other tissues, infection, the loss of the ability to perform sexually, death and other severe personal injuries, which are permanent and lasting in nature, including, but not limited to, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, a future of high-risk pregnancies, and any and all further medical complications, such as Plaintiff Loretta Cox's need for life-long medical treatment and care, and fear of developing further adverse health consequences.

80. Defendants manufactured, produced, promoted, formulated, created, developed, designed, sold, and distributed the Products without thoroughly and adequately testing them;

a. Defendants manufactured, produced, promoted, advertised, formulated, created, developed, designed, and distributed the Products while concealing and suppressing test results;

b. Defendants did not conduct sufficient studies and tests to determine whether the Products were safe for their intended uses, because Defendants knew, or should have known, that the Products were unsafe and unfit for use by reason of the dangers to their users;

c. Defendants failed to warn Plaintiff Loretta Cox, her physicians and her other healthcare providers, the medical and healthcare community, or the public as soon as Defendants knew, or should have known, that the dangers of the use of the Products were much higher than the risk of adverse effects from other, safer alternative treatments for stress urinary incontinence and pelvic organ prolapse;

d. Defendants concealed, suppressed, failed to warn about and failed to follow up on, the adverse results of clinical testing which determined that the Products had a high risk of serious and dangerous adverse health effects and consequences;

e. Defendants failed to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with and, more particularly, use the Products;

f. Defendants advertised and recommended the use of the Products while suppressing and concealing dangers they knew to be inherent in the use of transvaginal meshes;

g. Defendants represented that the Products were safe for their intended uses when Defendants knew, or should have known, that the Products were unsafe for their intended uses. Defendants represented that the Products were just as safe as other treatments for stress urinary incontinence and pelvic organ prolapse when Defendants knew, or should have known, that the Products had a high risk of serious and dangerous adverse health effects and consequences as a result of which Defendants' Products were not as safe as other treatments for stress urinary incontinence and pelvic organ prolapse;

h. Defendants suppressed, concealed, and omitted information concerning warnings, recommendations, and observations about the Products from Plaintiff Loretta Cox, her physicians, and her other healthcare providers and from the public, while knowing that the Products were unsafe and dangerous; and

i. Defendants suppressed, concealed, omitted, and misrepresented to Plaintiff Loretta Cox, her physicians and her other healthcare providers, the medical community, the public, the severity of the risks and the dangers inherent in the intended uses of the Products as compared to other treatments for stress urinary incontinence and pelvic organ prolapse.

81. Defendants were negligent in the design, research, development, manufacture, promotion, packaging, advertising, distribution, testing, marketing, and sale of the Products because:

a. Defendants failed to use due care in the design, research, manufacture, and development of the Products so as to avoid risks to patients of serious and dangerous adverse health effects and consequences when the Products were used for the treatment of stress urinary incontinence or pelvic organ prolapse;

b. Defendants failed to design and manufacture the Products so as to minimize the risk of serious side effects, including, but not limited to, the erosion of the vaginal wall and infections; and

c. Defendants failed to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance, to determine the safety of the Products.

82. While Defendants knew, or should have known, that the Products caused unreasonably dangerous side effects, Defendants nonetheless continued and still continue to market, manufacture, distribute, advertise, promote, and sell the Products to consumers.

83. Defendants knew, or should have known, that consumers such as Plaintiff Loretta Cox, into whom the Products were implanted, would foreseeably suffer severe injuries as a result of Defendants' failure to exercise ordinary care, as set forth above.

84. Defendants' negligence was the proximate cause of the injuries, harm, and economic loss that Plaintiff Loretta Cox has suffered and will continue to suffer in the future.

85. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions, and as the direct, foreseeable and proximate result of the implantation of Defendants' Products into Plaintiff Loretta Cox, Plaintiff Loretta Cox was caused to suffer, did suffer and will continue to suffer from physical, emotional, economic and other injury.

COUNT II
STRICT LIABILITY: DEFECTIVE DESIGN

86. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

87. At all relevant times, Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold and distributed the Products which were implanted into Plaintiff Loretta Cox.

88. Defendants' Products were expected to, and did, reach the intended consumers, handlers, and persons coming into contact with Defendants' Products without substantial change in the condition in which they were produced, manufactured, sold, distributed, labeled, and marketed by Defendants.

89. At all relevant times, Defendants' Products were manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous for use by the public, and, in particular, by Plaintiff Loretta Cox.

90. Defendants' Products, including, but not limited to, the Products implanted in Plaintiff Loretta Cox, were defective in design and formulation in that, when they left Defendants' hands, the foreseeable risks exceeded the benefits allegedly associated with the design of the Products.

91. Defendants' Products were defective in design because, when they left the Defendants' hands, they were unreasonably dangerous and also were more dangerous than the ordinary consumer would expect.

92. At all relevant times, Defendants' Products were in a defective condition and were unsafe, and Defendants knew, or should have known, that the Products were defective and unsafe, especially when used in the manner instructed and provided by Defendants.

93. Defendants knew, or should have known, at all relevant times, that the Products were in a defective condition, and were and are inherently dangerous and unsafe when used in the manner instructed and provided by Defendants.

94. At the time that the Products were implanted into Plaintiff Loretta Cox, they were being used for their intended uses in a manner normally intended, namely to treat stress urinary incontinence and pelvic organ prolapse.

95. Defendants had a duty to create products, including but not limited to the Products implanted in Plaintiff Loretta Cox, that were not unreasonably dangerous for their normal, common, intended uses.

96. Defendants' Products were manufactured defectively because they left the hands of Defendants in a defective condition and were unreasonably dangerous for their intended uses for which they were designed, manufactured and sold.

97. Defendants designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed the Products in such a way that they created an unreasonable risk to the health of consumers, and to Plaintiff Loretta Cox in particular, and Defendants are, therefore, strictly liable for the injuries and damages sustained by Plaintiff Loretta Cox.

98. Plaintiff Loretta Cox, her physicians and her other healthcare providers could not, by the reasonable exercise of care, have discovered the defects in the Products or perceived their danger.

99. Defendants' Products were defective due to inadequate warnings and instructions, because Defendants knew or should have known that the Products created a risk of serious and dangerous side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, loss of the ability to perform sexually, and other serious and severe personal injuries which are permanent and lasting in nature; and Defendants failed to test adequately for or to warn of these risks.

100. Defendants' Products were defective due to inadequate post-marketing surveillance and warnings because Defendants knew, or should have known, the risks of serious side effects, including, but not limited to, erosion of the vaginal wall and other

tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually.

101. Defendants also failed to provide adequate warning for use to consumers of the Products, and Defendants continue improperly to advertise, to market, to label, and to promote the Products to the public and to the medical community.

102. By reason of the foregoing, Defendants are strictly liable in tort to Plaintiffs.

103. The defective design of Defendants' Products and Defendants' over-marketing through advertisements, together with their failure to provide adequate warnings accompanying the Products were willful, wanton, and reckless.

104. The defects in Defendants' Products were substantial and contributing factors in causing Plaintiff Loretta Cox's injuries.

105. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions, and as the direct, foreseeable and proximate result of the implantation of the Products into Plaintiff Loretta Cox, Plaintiff Loretta Cox was caused to suffer, did suffer and will continue to suffer from physical, emotional, economic and other injury.

COUNT III
STRICT LIABILITY: FAILURE TO WARN

106. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

107. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released the

Products into the stream of commerce within the State of Massachusetts and elsewhere, and directly advertised and marketed within the State of Massachusetts and elsewhere, the Products to consumers or persons responsible for consumers, and, therefore, had a duty to warn of the risks associated with the use of the Products.

108. Defendants' Products were under the exclusive control of Defendants and were not accompanied by adequate warnings regarding adverse side effects and complications associated with the use of the Products, or by adequate warnings regarding the comparative severity, duration and extent of the risk of injuries associated with use of the Products.

109. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Products; no healthcare provider would have prescribed — and no consumer would have used — the Products had the facts concerning the safety and efficacy of the Products been made known to such healthcare providers and consumers.

110. Defendants' advertising campaign for the Products did *not* advise either consumers or healthcare providers that the Products presented multiple and dangerous medical risks, including erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually.

111. Defendants failed to perform or otherwise facilitate adequate testing; such testing which would have demonstrated that the Products posed serious and potential life threatening side effects and complications with respect to which full and proper warning

accurately and fully reflecting the symptoms, scope and severity should have been made to healthcare providers, to the FDA, and to consumers, including Plaintiff Loretta Cox.

112. The Products were defective due to inadequate post-marketing warnings and instructions because, after Defendants knew, or should have known, of the risk of serious and potentially life threatening side effects and complications from the use of the Products, Defendants failed to provide adequate warnings to healthcare providers or to the consuming public, including Plaintiff Loretta Cox, and instead continued to advertise and market the Products aggressively.

113. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff Loretta Cox has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT IV
BREACH OF EXPRESS WARRANTIES

114. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

115. Defendants expressly warranted that the Products were safe and fit for use by consumers, were of merchantable quality, did not produce dangerous side effects, and were adequately tested and fit for their intended uses.

116. At the time of Defendants' aforesaid express warranties, Defendants knew or should have known, that the Products did not conform to these express warranties

because the Products were not safe and had numerous serious side effects, about which Defendants did not adequately warn.

117. As a direct, foreseeable, and proximate result of Defendants' breach of their express warranties, Plaintiff Loretta Cox suffered and will continue to suffer severe and permanent personal injuries, harm and economic loss.

118. Plaintiff Loretta Cox relied on Defendants' express warranties with respect to the Products.

119. Members of the medical community, including Plaintiff Loretta Cox's physicians and other healthcare providers, relied upon Defendants' representations and warranties in connection with the use, recommendation, description, and implantation of the Products.

120. Defendants breached the express warranties because the Products were, and are, defective and unreasonably unsafe for their intended uses.

121. Defendants expressly represented to Plaintiff Loretta Cox, her physicians and her other healthcare providers that the Products (i) were safe and fit for the purposes intended, (ii) were of merchantable quality, (iii) did not produce any dangerous side effects in excess of those risks associated with other treatments for pelvic organ prolapse and stress urinary incontinence, and (iv) they were adequately tested and fit for their intended uses.

122. Defendants knew, or should have known, that their aforesaid representations and warranties were false, misleading, and untrue because the Products

were not safe and fit for their intended uses, and caused their users serious injuries of which Defendants did not adequately warn.

123. As a direct, foreseeable and proximate result of Defendants' foregoing acts and omissions, Plaintiff Loretta Cox was caused to suffer and did suffer serious and grievous personal injuries, including pelvic pain, infection, urinary problems, as well as other grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff Loretta Cox's need for life-long medical treatment and medical monitoring, and perpetual fear of developing additional adverse health consequences.

124. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff Loretta Cox has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT V
BREACH OF IMPLIED WARRANTIES

125. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

126. At all relevant times, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and sold the Products to treat pelvic organ prolapse and stress urinary incontinence.

127. At the time Defendants marketed, sold, and distributed the Products for implantation into Plaintiff Loretta Cox, Defendants knew of the intended uses of the Product, and impliedly warranted the Product to be of merchantable quality and safe and fit for such intended uses.

128. Defendants impliedly represented and warranted to Plaintiff Loretta Cox, her physicians and other healthcare providers, to the general public, that the Products were safe and of merchantable quality and fit for the ordinary purposes for which the Products were to be used.

129. Defendants' representations and warranties were false, misleading, and inaccurate because the Products were unsafe, unreasonably dangerous, improper, not of merchantable quality and otherwise defective.

130. Plaintiff Loretta Cox, her physicians and her other healthcare providers relied on Defendants' superior skill and judgment, as to whether the Products were of merchantable quality and safe and fit for their intended use, and as to whether the Products were fit for these particular uses.

131. Defendants put the Products into the stream of commerce within the State of Massachusetts and elsewhere, in a defective, unsafe, and inherently dangerous condition, and the Products were expected by Defendants to and did reach Plaintiff Loretta Cox without substantial change in the condition in which the Products were sold.

132. Defendants breached their implied warranty because the Products were not fit for their intended uses and/or purposes.

133. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions within the State of Massachusetts, Plaintiff Loretta Cox was caused to suffer, and did suffer, serious and dangerous side effects of vaginal pain, infection, urinary problems, permanent and substantial physical deformity, and may require corrective surgery. Plaintiff Loretta Cox has suffered other grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as her need for life-long medical treatment and care, medical monitoring, and perpetual fear of developing additional adverse health consequences.

134. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff Loretta Cox has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT VI
UNJUST ENRICHMENT

135. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

136. Defendants are, and at all times were, the manufacturer, seller, and/or supplier of the Products, including the Products implanted in Plaintiff Loretta Cox.

137. Plaintiff Loretta Cox paid for the Products for the purpose of treating her stress urinary incontinence and pelvic organ prolapse.

138. Defendants accepted payment from Plaintiff Loretta Cox for the purchase of the Products.

139. Plaintiff Loretta Cox has not received the safe and effective Products for which she paid. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiff Loretta Cox, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff Loretta Cox was not receiving the Products of the quality, nature or fitness that had been represented by Defendants or that Plaintiff Loretta Cox, as a reasonable consumer, expected.

140. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff Loretta Cox, who is entitled to in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT VII
COMMON LAW FRAUD

141. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

142. Defendants falsely and fraudulently represented to Plaintiff Loretta Cox, her physicians and her other healthcare providers, to the medical and healthcare communities, and to the public that the Products had been tested and had been

determined to be safe and effective to treat pelvic organ prolapse and stress urinary incontinence.

143. When Defendants made their aforesaid representations Defendants knew, or should have known, that those representations were false, and Defendants willfully, wantonly, and recklessly disregarded the falsity of their representations as well as the dangers and health risks to users of the Products, including Plaintiff Loretta Cox.

144. Defendants made the aforesaid representations with the intent of defrauding and deceiving Plaintiff Loretta Cox, her physicians and her other healthcare providers, the medical and healthcare communities, and the public, and to induce Plaintiff Loretta Cox, her physicians and her other healthcare providers, the medical and healthcare communities and the public, to recommend, purchase and implant the Products to treat pelvic organ prolapse and stress urinary incontinence, all of which evinced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff Loretta Cox and other consumers.

145. In representations to Plaintiff Loretta Cox, her physicians and her other healthcare providers, Defendants fraudulently concealed and intentionally omitted the following material information:

a. The Products are not as safe as other forms of treatment for pelvic organ prolapse and stress urinary incontinence;

b. The risk of adverse events with the Products was not adequately tested and was known by Defendants;

c. Defendants deliberately failed to follow up on the adverse results from clinical studies and buried and misrepresented those results;

d. Defendants were aware at all times of the dangers in the Products, in addition to, and above and beyond the risks normally associated with treating pelvic organ prolapse and stress urinary incontinence;

e. The Products were defective, and caused dangerous and adverse side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and loss of the ability to perform sexually, at a much more significant rate than other treatments for pelvic organ prolapse and stress urinary incontinence;

f. Patients with the Products implanted need to be monitored more regularly than patients treated with other treatments for pelvic organ prolapse and stress urinary incontinence;

g. The Products were manufactured negligently;

h. The Products were manufactured defectively; and

i. The Products were designed negligently and defectively.

146. Defendants had a duty to disclose to Plaintiff Loretta Cox, her physicians and her other healthcare providers, the defective nature of the Products, including, but not limited to, the fact that the Products had heightened risks of dangerous side effects.

147. Defendants had sole access to the facts concerning the defective nature of the Products and their propensity to cause serious and dangerous side effects and hence,

cause dangerous injuries and damage to persons into whom the Products were implanted, including Plaintiff Loretta Cox.

148. Defendants' aforesaid concealment and omissions of material fact concerning the safety of the Products were made intentionally, willfully, wantonly, and recklessly to mislead, to cause Plaintiff Loretta Cox's physicians and her other healthcare providers to purchase and to implant the Product, and to mislead Plaintiff Loretta Cox into reliance and to cause her to permit the Products to be implanted into her.

149. At the time that Defendants made these representations, and at the time the Products were implanted into Plaintiff Loretta Cox, Plaintiff Loretta Cox was unaware of the falsehood of Defendants' aforesaid representations, reasonably believed them to be true, and relied upon them.

150. Defendants knew, or should have known that the Products could and would cause severe and grievous personal injury to women into whom they were implanted and that the Products were inherently dangerous in a manner that exceeded any purported benefit from the use of the Products and any warnings gave concerning the Products.

151. In reliance upon Defendants' false representations, Plaintiff Loretta Cox was induced to, and did permit the Products to be implanted into her, thereby sustaining severe and permanent personal injuries and damages. Defendants knew, or should have known, that Plaintiff Loretta Cox, her physicians and her other healthcare providers had no way to determine that Defendants concealed and omitted facts necessary to make the statements Defendants made about the Products true.

152. Plaintiff Loretta Cox, her physicians and her other healthcare providers reasonably relied on Defendants' statements and representations which suppressed and concealed facts that were critical to understanding the dangers inherent in the use of the Products.

153. As a result of Defendants' research, clinical trials, testing or lack thereof, Defendants intentionally distributed false information and made false statements and representations, including, but not limited to, assuring Plaintiff Loretta Cox, her physicians, and her other healthcare providers and the public that the Products were safe to treat stress urinary incontinence and pelvic organ prolapse. Defendants intentionally omitted, concealed and suppressed the results of their research, clinical trials and testing from Plaintiff Loretta Cox, her physicians and her other healthcare providers and the public.

154. Defendants had a duty when disseminating information to the public, including Plaintiff Loretta Cox, to disseminate truthful information; and Defendants had a parallel duty not to deceive the public, Plaintiff Loretta Cox, her physicians, and her other healthcare providers.

155. The information Defendants distributed to Plaintiff Loretta Cox, her physicians, and her other healthcare providers, to the public, and to the medical community, included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing representations, which were materially false and

misleading, and which contained material omissions of the truth about the dangers of the use of the Products.

156. Defendants misrepresented to Plaintiff Loretta Cox, her physicians and her other healthcare providers, to the healthcare and medical communities, and to the public, the material facts that the Products did not have dangerous or serious adverse health safety concerns, and that the Products were as safe as other means of the treatment of pelvic organ prolapse and stress urinary incontinence.

157. Defendants' intent in making these misrepresentations was to deceive and defraud and to gain the confidence of Plaintiff Loretta Cox, her physicians and her other healthcare providers, the medical community, and the public and to induce Plaintiff Loretta Cox, her physicians and her other healthcare providers, the healthcare and medical communities, and the public to request, recommend, and implant the Products into patients, including Plaintiff Loretta Cox.

158. Defendants made claims and representations in reports to the public and to healthcare professionals and in advertisements that the Products did not present serious health risks.

159. Defendants' aforesaid representations were knowingly false when made or were made recklessly and without regard to the true facts.

160. Defendants' aforesaid representations were made with the intention of deceiving and defrauding Plaintiff Loretta Cox, her physicians and her other healthcare providers and other members of the healthcare and medical communities, were made in

order to induce Plaintiff Loretta Cox, her physicians and her other healthcare providers to dispense, recommend, and implant the Product into Plaintiff Loretta Cox.

161. Defendants intentionally concealed, omitted and misrepresented the dangerous and serious health and safety concerns inherent in the use of the Products for the purpose of influencing the sales of products known to Defendants to be dangerous and defective, and certainly not as safe as other alternatives for treating pelvic organ prolapse and stress urinary incontinence.

162. Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations, for the purpose of deceiving Plaintiff Loretta Cox, her physicians and her other healthcare providers, into a false sense of security, to induce Plaintiff Loretta Cox's physicians and other healthcare providers to recommend, dispense, and implant the Products into Plaintiff Loretta Cox, and to induce Plaintiff Loretta Cox to permit the Products to be implanted into her.

163. Plaintiff Loretta Cox and her healthcare providers relied to their detriment on Defendants' misrepresentations and omissions. Had Plaintiff Loretta Cox known the truth about the dangers and serious health and safety risks of the Products, she would not have permitted the Products to be implanted into her.

164. Defendants' fraud and deceit was perpetrated willfully, wantonly, and purposefully on Plaintiff Loretta Cox.

165. As a direct, foreseeable and proximate result of Defendants' aforesaid acts and omissions Plaintiff Loretta Cox was caused to suffer, and did suffer, the serious and dangerous side effects of vaginal pain, infection, urinary problems, permanent and

substantial physical deformity, will likely require corrective surgery, and suffered further grievous personal injuries, including, but not limited to, physical pain and mental anguish, permanently diminished enjoyment of life, and any and all additional life implications and complications, such as Plaintiff Loretta Cox's need for life-long medical treatment and care, medical monitoring and perpetual fear of developing additional adverse health consequences.

166. As a direct, foreseeable and proximate result of Defendants' foregoing conduct, Plaintiff Loretta Cox has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT VIII
NEGLIGENT MISREPRESENTATION

167. Plaintiffs incorporate each and every paragraph of this Complaint by reference as if fully stated herein and further state and allege as follows.

168. Defendants had the duty to accurately and truthfully represent to the medical and healthcare communities, to Plaintiff Loretta Cox, her physicians and her other healthcare providers, and to the public, that the Products had been tested and had been determined to be safe and effective for treating pelvic organ prolapse and stress urinary incontinence. Defendants' representations of safety and effectiveness of the Products were false.

169. Defendants failed to exercise ordinary care in their representations concerning the Products because Defendants negligently concealed, omitted and misrepresented the Products' high risk of unreasonable, dangerous, adverse side effects.

170. Defendants knew, or should have known, that the Products had been insufficiently tested, or had not been tested at all, lacked adequate and accurate warnings, and created a high risk, or higher than acceptable risk, or higher than reported and represented risk, of adverse side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and loss of the ability to perform sexually.

171. As a direct, foreseeable and proximate result of Defendants' wrongful acts and omissions, Plaintiff Loretta Cox has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

COUNT IX
LOSS OF CONSORTIUM

172. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

173. At all relevant times hereto, Plaintiff Loretta Cox had a spouse, Alfred Cox, who has suffered injuries and losses as a result of Plaintiff Loretta Cox's injuries.

174. Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications and other expenses associated with Plaintiff Loretta Cox's injuries.

175. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff Alfred Cox has been caused, presently and in the future, to suffer the loss of Plaintiff Loretta Cox's companionship, services, society, love and affection, and the ability of Plaintiff Alfred Cox and Plaintiff Loretta Cox has in those respects been impaired and depreciated. The marital association between husband and wife has been altered. Accordingly, Plaintiff Alfred Cox has been caused great mental anguish, economic loss, and other injury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages according to proof and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present;

2. Special damages according to proof and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including, permanent instability and loss of balance, and pain and suffering;

3. All other damages as allowed by law;

4. Disgorgement of profits; and

5. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and issues.

Dated: October 1, 2013

By their Attorneys

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